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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,037	01/22/2004	Robert J. Schwartz	HO-P02659US1	8488

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EXAMINER	
LONG, SCOTT	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,037	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-15* is/are rejected.

7)☒ Claim(s) *9 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/22/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Scott Long whose phone number is 571-272-9048.

Election/Restrictions

Examiner acknowledges the election, without traverse, of Group II directed to a method of diagnosing cardiac disease, in the reply filed on 4 May 2007.

Claim Status

Claims 1-4 and 16-41 are cancelled. Claim 9 is amended. Claims 5-15 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The new oath or declaration, having the signatures of all inventors, received on 18 June 2004 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 17 July 2007 consisting of 1 sheet are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit from provisional U.S. Application No. 60/441,668 (filed 01/22/2003). The instant application has been granted the benefit date, 22 January 2003, from the application 60/441,668.

Claim Objections

Claim 9 is objected to because of the following informalities: The examiner does not believe that the phrase, " is further defined as" adequately captures the intended meaning of the applicant, and suggests, "further comprises" or "is further comprised of". After all, the remainder of the claim language actually describes a further elaboration of the steps of the claimed method. Appropriate correction is required.

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. The examiner fails to see how redefining "cardiac disease" to mean "cardiac failure" further limits the claimed method. At best, this would be a change in scope of the intended use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drewett et al. (Journal of Biological Chemistry. 2001. Vol.276; No.36: 33444-33451) in view of Narula et al. (PNAS. July 1999. Col.96: 8144-8149).

Claim 5 is directed to a method of diagnosing cardiac disease in an individual, comprising the step of identifying cleavage of SRF in at least one cell from a sample from said individual.

Claim 6 is directed to the method of claim 5, wherein the sample is from a tissue of the individual.

Claim 7 is directed to the method of claim 6, wherein the tissue is cardiac tissue.

Claim 8 is directed to the method of claim 7, wherein the cardiac tissue is ventricular tissue.

Claim 9 is directed to the method of claim 5, wherein the identifying step is further defined as comparing levels of cleaved SRF in a sample from an individual suspected of having cardiac failure with a known control reflective of levels of cleaved SRF in non-failing cardiac tissue, wherein when said sample comprises elevated levels of cleaved SRF compared to said control, said individual suspected of having cardiac failure has a positive diagnosis for cardiac failure.

Claim 10 is directed to the method of claim 9, wherein the identifying step comprises immunoblot analysis for said cleaved SRF.

Claim 11 is directed to the method of claim 10, wherein the immunoblot analysis comprises an antibody against a region of SRF.

Claim 12 is directed to the method of claim 11, wherein the region of SRF is an N-terminal region or a C-terminal region.

Claim 13 is directed to the method of claim 12, wherein the N-terminal region comprises at least a portion of amino acid sequence encoded by the first coding exon of a SRF polynucleotide.

Claim 14 is directed to the method of claim 13, wherein the N-terminal region comprises SEQ ID NO:5.

Claim 15 is directed to the method of claim 5, wherein said cardiac disease is further defined as cardiac failure.

Drewett et al. teach, "these results indicate that SRE-dependent *c-fos* expression is down-regulated early in apoptosis and that...the fragments of SRF generated by caspase cleavage fail to maintain expression levels supported by full-length SRF" (page 33449, col.1) and further teach, "variations in the level of SRF fragments indicated that SRF cleavage might be a regulated event" (page 33445, col.2). Drewett et al. also describe analysis of SRF cleavage products in cells by immunoblotting with antibodies against the carboxyl- terminus or amino-terminus of SRF (page 33446, Fig.1). Drewett et al. further teach (uncleaved) SRF is required for normal functioning and development of muscle tissue (page 33444, col.2).

Narula et al. teach, "apoptosis has been shown to contribute to loss of cardiomyocytes in cardiomyopathy, progressive decline in the left ventricular function, and congestive heart failure... loss of myocytes contributes to myocardial dysfunction and is a predictor of adverse outcomes in the patients with congestive heart failure,

the present demonstration of an activated apoptotic cascade in cardiomyopathy could provide the basis for novel interventional strategies." (page 8144, abstract). Narula et al. further indicate, "protease cleavage...in the myocardial cytoplasmic extracts support the phenomenon of apotosis in end stage heart failure" (page 8148, col.1). Narula et al. teach comparison of biochemical analyses from tissue of normal and cardiac-diseased patients (page 8145, col.1). These patient tissues included ventricular tissue samples.

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Drewett et al. with Narula et al. to develop a method of diagnosing cardiac disease in an individual comprising the step of identifying cleavage of SRF in at least one cell from a sample from said individual.

The person of ordinary skill in the art would have been motivated to make those modifications because both references indicate an link between apoptosis and disease states. Narula et al. indicate the relationship between apoptosis and heart failure, while Drewett et al. describe the relationship between Serum Response Factor (SRF) cleavage and apoptosis. All of the details of the claimed invention are taught by the references, including immunoblotting with antibodies specific for N- or C-termini of SRF and comparisons of normal cardiac tissue and tissue from patients with end-stage cardiac failure.

The skilled artisan would have had a reasonable expectation of success in combining the teachings of Drewett et al. and Narula et al. because the methods and reagents are well characterized and commercially available. Furthermore, both

references adequately explain the relationship of apoptosis to disease and methodologies used in their biochemical analyses.

Therefore the method as taught by Drewett et al. in view of Narula et al. would have been *prima facie* obvious over the method of the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JLE